

listing of D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, effective April 28, 1981.

(n) *D&C Blue No. 6*. The Commissioner of Food and Drugs, having concluded that unresolved questions remain concerning the chemistry of unidentified minor components, hereby terminates the provisional listing of D&C Blue No. 6 for use in drugs and cosmetics.

(o) *D&C Green No. 6*. In the absence of a petition to list D&C Green No. 6 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listing of D&C Green No. 6 for use in ingested drugs and cosmetics, effective March 27, 1981.

(p) [Reserved]

(q)(1) *D&C Red No. 19 and D&C Red No. 37*. Having concluded that, when ingested, D&C Red No. 19 causes cancer in rats and mice, the agency hereby terminates the provisional listings of D&C Red No. 19 and chemically related D&C Red No. 37 for use in ingested drugs and ingested cosmetics, effective February 4, 1983.

(2) *D&C Red No. 37*. In the absence of a petition to list D&C Red No. 37 for external uses, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of D&C Red No. 37 for use in externally applied drugs and cosmetics, effective June 6, 1986.

(r) [Reserved]

(s) *D&C Orange No. 17*. Having concluded that, when ingested, D&C Orange No. 17 causes cancer in rats and mice, the agency has terminated the provisional listing of D&C Orange No. 17 for use in ingested drugs and ingested cosmetics, effective March 31, 1983.

(t) *D&C Red No. 8 and D&C Red No. 9*. In the absence of a petition to list D&C Red No. 8 and D&C Red No. 9 for mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of D&C Red No. 8 and

D&C Red No. 9 for use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, effective January 6, 1987.

(u) *FD&C Red No. 3*. Having concluded that FD&C Red No. 3 causes cancer in rats, the agency hereby terminates the provisional listing of FD&C Red No. 3 for use in cosmetics and externally applied drugs and the provisional listing of the lakes of FD&C Red No. 3 for use in food, drug, and cosmetic products, effective January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For Federal Register citations affecting §81.10, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§81.30 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list (§81.10(a)) are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b)(1) Certificates issued heretofore for the color additive designated FD&C Red No. 1 are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

(c) Certificates issued for FD&C Red No. 4 and all mixtures containing this color additive are cancelled and have no effect after September 23, 1976 insofar as food, ingested drugs, and ingested cosmetics are concerned, and use of this color additive in the manufacture of food, ingested drugs, and ingested cosmetics after this date will result in adulteration. The certificates shall continue in effect for the use of FD&C Red No. 4 in externally applied

drugs and cosmetics. The Commissioner finds, on the basis of the scientific evidence before him that no action has to be taken to remove from the market food, ingested drugs and ingested cosmetics containing the color additive.

(d) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after October 4, 1966, and use of such color additives in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration:

FD&C Green No. 1.
FD&C Green No. 2.
D&C Green No. 7.
D&C Red No. 5.
D&C Red No. 14.
D&C Red No. 18.
D&C Red No. 24.
D&C Red No. 29.
D&C Red No. 35.
D&C Red No. 38.
D&C Orange No. 3.
D&C Orange No. 8.
D&C Orange No. 14.
D&C Orange No. 15.
D&C Orange No. 16.
D&C Blue No. 7.
D&C Black No. 1.
Ext. D&C Yellow No. 5.
Ext. D&C Yellow No. 6.
Ext. D&C Red No. 1.
Ext. D&C Red No. 2.
Ext. D&C Red No. 3.
Ext. D&C Red No. 10.
Ext. D&C Red No. 11.
Ext. D&C Red No. 13.
Ext. D&C Red No. 14.
Ext. D&C Red No. 15.
Ext. D&C Blue No. 1.
Ext. D&C Blue No. 4.
Ext. D&C Orange No. 1.
Ext. D&C Orange No. 4.

(e) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after July 1, 1968, and use of such color additives in the manufacture of drugs or cosmetics after that date will result in adulteration:

Ext. D&C Yellow No. 3.
Ext. D&C Red No. 8.
Ext. D&C Orange No. 3.

(f) Certificates issued for D&C Yellow No. 11 and all mixtures containing this color additive are canceled and have no effect after April 30, 1968, insofar as in-

gested use is concerned. Use of this color additive in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(g) Certificates issued for D&C Red No. 17, D&C Red No. 31, D&C Red No. 34, D&C Orange No. 4, and D&C Violet No. 2, and all mixtures containing these color additives, are canceled and have no effect after December 31, 1968, insofar as ingested use is concerned. Use of these color additives in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(h)(1) Certificates issued for FD&C Violet No. 1 and all mixtures containing this color additive are canceled and have no effect after April 10, 1973, and use of such color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him.

(i) Certificates issued prior to July 1, 1968, for D&C Brown No. 1 and Ext. D&C Violet No. 2 and all mixtures containing these colors are canceled and have no effect. This cancellation does not apply to certificates issued after March 15, 1973, for D&C Brown No. 1 and Ext. D&C Violet No. 2, which are provisionally listed in § 81.1(b) and (c) respectively for coloring externally applied cosmetics.

(j)(1) Certificates issued for FD&C Red No. 2 and all mixtures containing this color additive are canceled and have no effect after January 28, 1976, and use of this color additive in the manufacture of food, drugs, or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market food, drugs, and cosmetics containing the color additive.

(k)(1) Certificates issued for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, their lakes and

all mixtures containing these color additives or their lakes are cancelled and have no effect after December 13, 1977, and use of these color additives in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market, drug and cosmetic products containing the color additives.

(l)(1) Certificates issued for Ext. D&C Yellow No. 1 and all mixtures containing this color additive are cancelled and have no effect after December 13, 1977, and use of this color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(m)(1) Certificates issued for Ext. D&C Green No. 1 and all mixtures containing this color additive are cancelled and have no effect after November 29, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(n)(1) Certificates issued for D&C Orange No. 10, D&C Orange No. 11, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after April 28, 1981 and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additives were added on or before April 28, 1981.

(o)(1) Certificates issued for D&C Blue No. 6 and all mixtures containing this color additive are cancelled insofar as its use in drugs and cosmetics is

concerned and have no effect after December 13, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration. The color will continue to be certified for use in the coloring of surgical sutures.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(p)(1) Certificates issued for D&C Green No. 6, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after May 4, 1982 and use of the color additive in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics containing the color additive.

(q) [Reserved]

(r)(1) Certificates issued for D&C Red No. 19 and D&C Red No. 37, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after February 4, 1983, and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics to which D&C Red No. 19 and D&C Red No. 37 were added on or before February 4, 1983, or externally applied drugs and cosmetics to which D&C Red No. 37 was added on or before June 6, 1986.

(3) Certificates issued for D&C Red No. 37, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after June 6, 1986, and use of this color additive in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) Certificates issued for D&C Red No. 19, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(5) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Red No. 19 was added on or before July 15, 1988.

(s)(1) Certificates issued for D&C Red No. 8 and D&C Red No. 9, their lakes, and all mixtures containing these color additives are canceled and have no effect as pertains to their use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after January 6, 1987, and use of these color additives in the manufacture of mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market mouthwash, dentifrices, and ingested drugs to which the color additives were added on or before January 6, 1987. Ingested drug lip products, however, are regulated for use in §§ 74.1308 and 74.1309.

(3) Certificates issued for D&C Red No. 8, and D&C Red No. 9, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drug and cosmetic lip products and in externally applied drugs and cosmetics after July 15, 1988, and use of these color additives in the manufacture of ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics after this date will result in adulteration.

(4) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drug and cosmetic lip products and externally applied drugs and cosmetics to which the color additives were added on or before July 15, 1988.

(t)(1) Certificates issued for D&C Orange No. 17, its lakes, and all mixtures

containing this color additive are cancelled and have no effect as pertains to its use in ingested drugs and ingested cosmetics after March 31, 1983 and use of this color additive in the manufacture of ingested drugs or ingested cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additive was added on or before March 31, 1983.

(3) Certificates issued for D&C Orange No. 17, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Orange No. 17 was added on or before July 15, 1988.

(u)(1) Certificates issued for FD&C Red No. 3 and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in cosmetics and externally applied drugs after January 29, 1990. Certificates issued for FD&C Red No. 3 lakes and all mixtures containing these lakes are cancelled and have no effect as pertains to their use in food, drugs, and cosmetics after January 29, 1990. Certificates issued for D&C Red No. 3 lakes and all mixtures containing those lakes are cancelled and have no effect as pertains to their use in drugs and cosmetics after January 29, 1990. Use of this color additive in the manufacture of cosmetics and of externally applied drugs and any use of the lakes of FD&C Red No. 3 (including the lakes of D&C Red No. 3) after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action must be taken to remove from the market food, drugs, and cosmetics to which the provisionally listed color additive or its lakes were added on or before January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

§ 81.32

EDITORIAL NOTE: For Federal Register citations affecting §81.30, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§81.32 Limitation of certificates.

Certificates issued for the color additives listed in §81.25 and for all mixtures containing these color additives are limited to the conditions stated in §81.25. The use of these color additives in drugs and cosmetics in any other manner will result in adulteration. Each of these color additives shall bear a label statement of the tolerance and use limitations applicable to it.

[44 FR 48966, Aug. 21, 1979]

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

Subpart A—General Provisions

Sec.

82.3 Definitions.

82.5 General specifications for straight colors.

82.6 Certifiable mixtures.

Subpart B—Foods, Drugs, and Cosmetics

82.50 General.

82.51 Lakes (FD&C).

82.101 FD&C Blue No. 1.

82.102 FD&C Blue No. 2.

82.203 FD&C Green No. 3.

82.304 FD&C Red No. 4.

82.705 FD&C Yellow No. 5.

82.706 FD&C Yellow No. 6.

Subpart C—Drugs and Cosmetics

82.1050 General.

82.1051 Lakes (D&C).

82.1104 D&C Blue No. 4.

82.1205 D&C Green No. 5.

82.1206 D&C Green No. 6.

82.1254 D&C Orange No. 4.

82.1255 D&C Orange No. 5.

82.1260 D&C Orange No. 10.

82.1261 D&C Orange No. 11.

82.1306 D&C Red No. 6.

82.1307 D&C Red No. 7.

82.1317 D&C Red No. 17.

82.1321 D&C Red No. 21.

82.1322 D&C Red No. 22.

82.1327 D&C Red No. 27.

82.1328 D&C Red No. 28.

82.1330 D&C Red No. 30.

82.1331 D&C Red No. 31.

82.1333 D&C Red No. 33.

82.1334 D&C Red No. 34.

82.1336 D&C Red No. 36.

21 CFR Ch. I (4–1–98 Edition)

82.1602 D&C Violet No. 2.

82.1707 D&C Yellow No. 7.

82.1708 D&C Yellow No. 8.

82.1710 D&C Yellow No. 10.

Subpart D—Externally Applied Drugs and Cosmetics

82.2050 General.

82.2051 Lakes (Ext. D&C).

82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§82.3 Definitions.

For the purposes of this part:

(a)–(f) [Reserved]

(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.

(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.

(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

§82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for